STERIS®

510(k) Summary
For
Verify® SCBI 275F 3-10

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Summary Date: July 23, 2009

1. Device Name

Trade Name: Verify® SCBI 275F 3-10

Common/usual Name: Biological Indicator

Classification Name: Biological Sterilization Process Indicators (21 CFR 880.2800), Product Code FRC

2. Predicate Device

- K051056, Verify® Dual Series SCBI cleared as Verify® Self-Contained Biological Indicator
- K855101, Verify® Dual Series SCBI cleared as Verify® Self-Contained Biological Indicator cleared as Assert™ Biological/Chemical Indicator
- K963841, SGM EZTest Steam BI

3. Description of Device

The proposed Verify® SCBI 275F 3-10 is a self-contained biological indicator intended for use in microbial qualification and routine monitoring of steam sterilization processes. The proposed Verify® SCBI 275F 3-10 consists of a plastic vial that contains a disc inoculated with *Geobacillus stearothermophilus* spores and an ampoule of culture media.

This 510(k) premarket notification was submitted to expand the Indications For Use for the biological indicator to include 275°F (135°C) steam sterilization for 3 minute Gravity Flash and Pre-vacuum cycles, and 10 minute Gravity and Gravity Flash cycles.

4. Intended Use

The Verify® SCBI 275F 3-10 is a self-contained biological indicator that may be used for installation testing and routine monitoring of steam sterilizers. The Verify® SCBI 275F 3-10 provides independent confirmation that sterilization conditions were achieved during the following cycles:

TEMPERATURE	STERILIZATION TYPE	TIME
275°F (135°C)	Gravity Flash	3 minutes
275°F (135°C)	Prevacuum	3 minutes
275°F (135°C)	Gravity	10 minute
275°F (135°C)	Gravity Flash	10 minutes

5. Description of Safety and Substantial Equivalence

The proposed Verify® SCBI 275F 3-10 is identical in components, design, materials, and manufacturing specifications to the predicates K051056, Verify® Dual Series SCBI and K855101 (the predicate to K051056). It has the same cycle temperature as the predicate K963841, SMG EZTest.

Performance testing was conducted to validate the SCBI for use in the steam sterilization cycles listed in the Intended Use section. The results support the use of the SCBI for monitoring these cycles and confirm that the SCBI meets the current requirements of FDA guidance and relevant industry standards.

The proposed Verify® SCBI 275F 3-10 does not have any characteristics that would introduce concerns for safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. John Robert Scoville, JR
Fellow Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060

SEP - 1 2009

Re: K083665
Trade/Device Name: Verify® SCBI 275F 3-10
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: July 23, 2009
Received: July 28, 2009

Dear Mr. Scoville:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson per

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infusion Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Verify® SCBI 275F 3-10

Indications for Use:

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Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083665

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